Endo Presents New Qwo® (collagenase clostridium histolyticum-aaes) Data at the American Society for Dermatologic Surgery's Annual Meeting

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DUBLIN, Oct. 7, 2022 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that data from studies of Endo Aesthetics' Qwo® (collagenase clostridium histolyticum-aaes), an FDA-approved injectable for the treatment of moderate to severe cellulite in the buttocks of adult women, will be presented during the American Society for Dermatologic Surgery annual meeting, taking place now through October 10 in Denver, CO.

The five new and modified oral presentations are below:

- **NEW:** Durability of Collagenase Clostridium Histolyticum-aaes Treatment of Buttock Cellulite in Women: Open-Label Extension Study Results Through 3 Years
  - Authors: Michael H. Gold, MD; David Hernandez, MD; Saji Vijayan, MBBS; Qinfang Xiang, PhD; Joely Kaufman-Janette, MD; Sabrina Guillen Fabi, MD
- **NEW:** Capturing Cellulite: A Practical Photography Guide for the General Aesthetics Practice
  - Authors: Sabrina Guillen Fabi, MD, FAAD, FAACS; Autumn Murphy, BA; Jill Edgecombe, BS; Mitchel P. Goldman, MD
- **NEW:** Visualizing the Arborisation of Subdermal Septa: A Closer MRI View into the 3-Dimensionality Behind Cellulite
  - Authors: Sebastian Cotofana, MD, PhD; Jill Edgecombe, BS; David Hernandez, MD; Lisa Metler, PA-C; Michael Alfertshofer, MD
- A Phase 2 Open-Label Study of Bruising Following Different Interventions With Collagenase Clostridium Histolyticum-aaes Treatment for Cellulite of the Buttocks in Women
  - Authors: Joely Kaufman-Janette, MD; Michael H. Gold, MD; David Hernandez, MD; Carrie Lewis, MS; Gongfu Zhou, PhD; James P. Tursi, MD; Saji Vijayan, MBBS, D. Diab
- Direct Visualization of Dermal Thickness, Cellulite, and Fibrous Bands Using High-Resolution Ultrasound
  - Authors: Lisa Metler, PA-C; Serena Chase, MBA; Jill Edgecombe, BS; Brad Bengtson, MD

INDICATION
Qwo® is indicated for the treatment of moderate to severe cellulite in the buttocks of adult women.

IMPORTANT SAFETY INFORMATION FOR QWO

CONTRAINDICATIONS
QWO is contraindicated in patients with a history of hypersensitivity to collagenase or to any of the excipients or the presence of infection at the injection sites.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions
Serious hypersensitivity reactions including anaphylaxis have been reported with the use of collagenase clostridium histolyticum. If such a reaction occurs, further injection of QWO should be discontinued and appropriate medical therapy immediately instituted. Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions.

Injection Site Bruising
In clinical trials, 84% of subjects treated with QWO experienced injection site bruising. Subjects with coagulation disorders or using anticoagulant or

antiplatelet medications (except those taking ≤150 mg aspirin daily) were excluded from participating in Trials 1 and 2.

QWO should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet (except those taking ≤150 mg aspirin daily) or anticoagulant therapy.

Substitution of Collagenase Products
QWO must not be substituted with other injectable collagenase products.
QWO is not intended for the treatment of Peyronie's Disease or Dupuytren's Contracture.

ADVERSE REACTIONS
In clinical trials, the most commonly reported adverse reactions in patients treated with QWO with an incidence ≥ 10% were at the injection site: bruising, pain, nodule and pruritus.

Click for Full Prescribing Information for QWO.

About Cellulite
Cellulite is a localized alteration in the contour of the skin that has been reported in over 90 percent of post-pubertal females and affects women of all races and ethnicities.[1,2] The presence of cellulite is associated with changes in dermal thickness and in the fat cells and connective tissue below the skin.[3] A primary factor in the cause of the condition is the collagen containing septae which attach the skin to the underlying fascia layers.[4,5] The septae tether the skin which, with additional contributing protrusions of subcutaneous fat, causes the surface dimpling characteristic of cellulite.[6] These fibrous septae are oriented differently with varying thickness in females than in males, which informs our understanding of cellulite as a gender-related condition.[7] Cellulite clinically presents on the buttocks, thighs, lower abdomen and arms.[8]

It is known that cellulite is different from generalized obesity.[8] In generalized obesity, adipocytes undergo hypertrophy and hyperplasia that is not limited to the pelvis, thighs, and abdomen.[2] In areas of cellulite, characteristic large, metabolically stable adipocytes have physiologic and biochemical properties that differ from adipose tissue located elsewhere.[9] An anatomical study in 2019 found that women have increased fat lobule height compared with men, which may also contribute to the mattress-like appearance seen as a result of the tension of the fibrous septae.[7] Weight gain can make cellulite more noticeable, but cellulite may be present even in thin subjects.[8]

About Endo Aesthetics
Endo Aesthetics is embarking on a mission devoted to pushing the boundaries of aesthetic artistry. Driven by world-class research and development, Endo Aesthetics is advancing solutions to address unmet needs beginning with the first FDA-approved injectable treatment for cellulite in the buttocks. Endo Aesthetics is an Endo International plc (OTC: ENDPQ) business. Learn more at www.endoaesthetics.com.

About Endo
Endo (OTC: ENDPQ) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at www.endo.com or connect with us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements
Certain information in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation, including, but not limited to, the presentation of data from studies and any other statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect the Company's current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the following: the outcome of the Company's contingency planning and restructuring activities; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust related matters; actual or contingent liabilities; settlement discussions or negotiations; the Company's liquidity, financial performance, cash position and operations; the Company's strategy; risks and uncertainties associated with Chapter 11 proceedings; the negative impacts on the Company's businesses as a result of filing for and operating under Chapter 11 protection; the time, terms and ability to confirm a sale of the Company's businesses under Section 363 of the U.S. Bankruptcy Code; the adequacy of the capital resources of the Company's businesses and the difficulty in forecasting the liquidity requirements of the operations of the Company's businesses; the unpredictability of the Company's financial results while in Chapter 11 proceedings; the Company's ability to discharge claims in Chapter 11 proceedings; negotiations with the holders of the Company's indebtedness and its trade creditors and other significant creditors; risks and uncertainties with performing under the terms of the restructuring support agreement and any other arrangement with lenders or creditors while in Chapter 11 proceedings; the Company's ability to conduct business as usual; the Company's ability to continue to serve customers, suppliers and other business partners at the high level of service and performance they have come to expect from the Company; the Company's ability to continue to pay employees, suppliers and vendors; the ability to control costs during Chapter 11 proceedings; adverse litigation; the risk that the Company's Chapter 11 Cases may be converted to cases under Chapter 7 of the Bankruptcy Code; the Company's ability to secure operating capital; the Company's ability to take advantage of opportunities to acquire assets with upside potential; the Company's ability to execute on its strategic plan to pursue, evaluate and close an asset sale of the Company's businesses pursuant to Section 363 of the U.S. Bankruptcy Code; the impact of competition, including the loss of exclusivity and generic competition for VASOSTRICT®; our ability to satisfy judgments or settlements or pursue appeals including bonding requirements; our ability to adjust to changing market conditions; our ability to attract and retain key personnel; our inability to maintain compliance with financial covenants and operating obligations which would expose us to potential events of default under our outstanding indebtedness; our ability to incur additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes; our ability to refinance our indebtedness; a significant reduction in our short-term or long-term revenues which could cause us to be unable to fund our operations and liquidity needs or repay indebtedness; supply chain interruptions or difficulties; changes in competitive or market conditions; changes in legislation or regulatory developments; our ability to obtain and maintain adequate protection for our intellectual property rights; the timing and uncertainty of the results of both the research and development and regulatory processes, including regulatory decisions, product recalls, withdrawals and other unusual items; domestic and

foreign health care and cost containment reforms, including government pricing, tax and reimbursement policies; technological advances and patents obtained by competitors; the performance, including the approval, introduction, and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; our ability to integrate any newly acquired products into our portfolio and achieve any financial or commercial expectations; the impact that known and unknown side effects may have on market perception and consumer preference for our products; the effectiveness of advertising and other promotional campaigns; the timely and successful implementation of any strategic initiatives; unfavorable publicity regarding the misuse of opioids; the uncertainty associated with the identification of and successful consummation and execution of external corporate development initiatives and strategic partnering transactions; our ability to advance our strategic priorities, develop our product pipeline and continue to develop the market for QWO® and other products; and our ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner. In addition, U.S. and international economic conditions, including consumer confidence and debt levels, inflation, taxation, changes in interest and currency exchange rates, international relations, capital and credit availability, the status of financial markets and institutions, the impact of and response to the ongoing COVID-19 pandemic and the impact of continued economic volatility, can materially affect our results. Therefore, the reader is cautioned not to rely on these forward-looking statements. Endo expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law.

References:

1. Hexsel DM Abreu M, Rodrigues TC, et al. Side-by-side comparison of areas with and without cellulite depressions using magnetic resonance imaging. *Dermatol Surg.* 2009;35(10):1471-7.
2. Khan MH, Victor F, Rao B, et al. Treatment of cellulite: Part I. Pathophysiology. *J Am Acad Dermatol.* 2010;62(3):361-70.
3. Querleux B, Cornillon C, Jolivet B, et al. Anatomy and physiology of subcutaneous adipose tissue by in vivo magnetic resonance imaging and spectroscopy: Relationships with sex and presence of cellulite. *Skin Res Technol.* 2002;8(2):118-24.
4. Zhang YZ, Ran LY, Li CY, et al. Diversity, structures, and collagen-degrading mechanisms of bacterial collagenolytic proteases. *Appl Environ Microbiol.* 2015;81(18):6098-6107.
5. Rossi AM, Katz BE. A modern approach to the treatment of cellulite. *Dermatol Clin.* 2014;32(1):51-59.
6. Hexsel D, Zechmeister do Prodo D, Goldman M. Topical Management of Cellulite. In: Goldman M, Hexsel D, eds. *Cellulite: Pathophysiology and Treatment. 2nd ed.* Boca Raton: CRC Press; 2010:62-68.
7. Rudolph C, Hladik C, Hamade H, et al. Structural gender-dimorphism and the biomechanics of the gluteal subcutaneous tissue: Implications for the pathophysiology of cellulite. *Plast Reconstr Surg.* 2019;143(4):1077-86.
8. Avram MM. Cellulite: a review of its physiology and treatment. *J Cosmet Laser Ther*. 2005;7:1-5.
9. Pierard GE, Nizet JL, Pierard-Franchimont C. Cellulite: from standing fat herniation to hypodermal stretch marks. *Am J Dermatopathol.* 2000;22(1):34-7.

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